## REMARKS

### 1. Status of Application

The status of the application referred to in the priority claim has been updated to reflect that the present application is a "continuation-in-part" of Application No. 09/694404 and that Application No. 09/694404 is now US Patent No. 6426406. No new matter has been added.

As the present application is a continuation-in-part type application, a new substitute Declaration will be submitted upon the allowance of the claims.

### 2. Specification Amendments

In the paragraph on page 5, line 16-29, "filed" has been changed to "field". No new matter has been added by correcting this obvious typographical error.

In the paragraphs on Page 11, lines 5-13 and Page 15, lines 22-29, Applicant has inserted parts of the text from original Claim 1, step (c) so to provide a clear antecedent base for the limitations in the claims. Growing a crystal to a desired size is obvious to those with ordinary skill in the art (as the examiner noted). No new matter has been added as this material was contained in Claim 1 as originally filed.

Further, Applicant maintains the text on page 11, lines 9-10 provides an antecedent basis for this particular claim limitation as the process is disclosed as a process that is used to "cause nucleation and crystal growth."

### 3. Claim Amendments.

The claims have been amended to remove minor typographical errors and in some cases to provide proper antecedent basis for the claim limitations. These clarifications should address the examiner's 35 USC 112 concerns and Applicant requests that the examiner withdraw the objection to Claim 1 and 11 based on 35 USC 112. No new matter has been added to the claims.

New Claim 21 is based on the Specification and Claims as originally filed and no new matter has been added.

## 4. Description of the Invention to Aid the Examin r.

Before specifically addressing the examiner's comments, Applicant would like to help elucidate the differences between Applicant's two lines of inventions. One line of invention is represented in the present application and certain of Applicant's other patent applications and issued patents, including some of the references cited by the examiner in the current Office Action. Another line of invention is represented in other patent applications and patents, including some of the references cited by the examiner in the current Office Action. Applicant submits that there are two significant points that may help clear up the differences between Applicant's invention and the cited art.

There are two lines of applications that cover the two independent lines of inventions. The first line of applications (e.g. Myerson '406 and the present invention) we call the **Polymorph Line**. The Polymorph Line covers methods for nucleating polymorph crystals - that is the inventive method is a novel method for preparing polymorphs that are not otherwise able to be prepared under traditional conditions and for preparing heretofore unknown polymorphs. As such, the Polymorph Line can be used to prepare novel crystal polymorphs that are not ordinarily present by the use of a laser to induce the formation of the polymorph. In many cases, Applicant's Polymorph Line provides a unique method to produce novel crystal compounds. The Polymorph Line of applications was invented by Drs. Myerson and Garetz.

The second line of applications (e.g. Myerson '935) we call the **Protein Crystal Line**. The Protein Crystal Line covers methods for the nucleation of protein crystals irrespective of crystal structure and is used to prepare better (larger and purer) crystals that would otherwise normally nucleate in a solution by known methods. In fact, the purpose of the Protein Crystal Line of inventions is stated in at least one of the specifications, that is to "produce protein crystals of superior quality and larger size". Thus, by definition, the Protein Crystal Line is for producing improved versions of known crystals. In the Protein Crystal Line of inventions, a user selects wavelengths of light that can induce the nucleation of an improved crystal and can improve the time it takes to produce a crystal, irrespective of the type of crystal and specifically irrespective of the polymorphism of the crystal. Polymorphism simply is not relevant to the Protein Crystal

Line. The Protein Crystal Line of applications has been invented by solely by Dr. Myerson.

A comparative review of the claims of each line of inventions unequivocally shows that the inventions are distinct from one another. The claims in the Polymorph Line are directed to the creation of polymorphs. The claims in the Protein Crystal Line are directed to the creation of larger and/or higher purity protein crystals. While both lines of methods use the same basic tools (the laser and some process steps), the results obtain are completely different. This is common in the filed of these inventions as most chemistry labs contain the same general array of equipment. However, the manner in which the tools are used and the solutions selected result in the different inventions. In the Polymorph Line, the inventors were trying (and were successful) in producing polymorphs of crystals. In the Protein Crystal Line, the inventor was trying (and was successful) in producing protein crystals of larger size and/or higher purity. One does not anticipate or obviate the other.

In other words, in the Polymorph Line, the invention is to take a solution of a known substance and subject it to light so as to induce the nucleation of a polymorph. In the Protein Crystal Line, the invention is to take a solution of a protein, subject it to light so as to induce the nucleation of a protein crystal not only irrespective of polymorphism but also with the intent that the nucleated protein crystal is the commonly nucleated protein crystal, and to grow the crystal. One of ordinary skill in the art would not assume a polymorph-producing method would be use to induce and grow higher quality protein crystals or that a protein crystal-producing method would be used to induce polymorphs. Thus, one of ordinary skill in the polymorph art would not look to the protein crystal art, and vice versa.

## 5. Disclaimers

### A. Claims 1-20 have been disclaimed beyond the end of the term of Myerson '406.

Applicant has filed a terminal disclaimer, in accordance with 37 CFR 1.321(c), contemporaneously with this Response that disclaims any portion of the term connected with Claims 1-21 that extends beyond the end of the term of US Patent No. 6426406

(Myerson '406), which is the parent to the current patent application. As such, Applicant requests that the examiner withdraw the rejection based on the judicially created doctrine of obviousness type double patenting over the claims of Myerson '406.

**B. Claims 1-12, 19, and 20 have been disclaimed the end of the term of Myerson '751.**

Applicant has filed a terminal disclaimer, in accordance with 37CFR 1.321(c), contemporaneously with this Response that disclaims any portion of the term connected with Claims 1-12, 19, and 20 that extends beyond the end of the term of US Patent Application No. 09/965751 (Myerson '751), which is a cousin to the current patent application. As such, Applicant requests that the examiner withdraw the provisional rejection based on the judicially created doctrine of obviousness type double patenting over the claims of Myerson '751.

**C. A Terminal Disclaimer is NOT being filed and is not necessary regarding Claims 1-12, 19, and 20 relative to Myerson '935.**

As explained above in Section 4 and as discussed below in Section 6, US Patent Application No. 09/918935 (Myerson '935) is not a Polymorph Line invention, but is a Protein Crystal Line invention. As such, it is patentably distinct from the present invention and does not anticipate or obviate the present invention.

## 6. 35 USC 102 Rejections

Anticipation under 35 USC 102(b) requires "the disclosure in a prior art reference each and every element of the claimed invention." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081 (Fed. Cir. 1986); *see also verdegall Bros. V. Union Oil Co. of California,* 814 F2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) ("a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference"). The absence of one element from the cited prior reference negates anticipation. *See Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 224 USPQ2d 409 (Fed Cir. 1984). Further, the Examiner may not apply a theory analogous to the Doctrine of Equivalents to anticipate a claim. *See Richardson v. Suzuki Motor Co., Ltd.*, 3 USPQ2d 1766 (Fed. Cir 1987) (Federal Circuit held district court erred by instructing jury that anticipation could be

found "by equivalents"). Also, when determining anticipation under 35 USC 102(b), the Examiner may not combine references. *Continental Can Co. USA, Inc.*, 20 USPQ2d 1746 (Fed Cir 1991). Anticipation was intended to apply in the limited situations in which one reference incorporates all the element of a claim in a subsequent invention because the nonobvious standard was intended to cover broader obvious leaps from a reference to a claim or from combined references to a claim. *See Titanium Metals Corp. v. Brenner*, 227 USPQ 773 (Fed. Cir. 1985).

Prior art for the purposes of anticipation is pertinent art recognized by persons of ordinary skill to be in the ***field of the invention***. *See In re Spada* 15 USPQ2d 1655, 1657 (Fed.Cir.1990). Prior art is pertinent if persons of ordinary skill in the art would have consulted art in that field to develop the invention given the nature of the problem. *See In re Paulsen*, 31 USPQ2d 1671 (Fed. Cir. 1994). Specifically, the pertinence of any reference is dependent upon whether it would suggest to persons skilled in the art to do the thing that the applicant has done, and the same is true in considering more than one reference or a reference alleged not to be in the particular art. *See In re Phipps*, 69 USPQ 88 (CCPA 1946).

The federal circuit has applied anticipation narrowly. For example, the Federal Circuit affirmed a district court determination that patents related to a ceramic welding process for repairing industrial furnaces were not invalid for anticipation, notwithstanding that the claims of the patents overlapped with or read on either or both of two prior art patents, because the district court properly determined that the prior art patents were related to flame-spraying and to combustion at the furnace wall. *See Glaverbel Societe Anonyme And Fosbel, Inc. v. Northlake Marketing & Supply, Inc.*, 33 USPQ2d 1496 (Fed Cir. 1995). Even though both inventions had a general relation to combustion, they were not so related that one of ordinary skill in the ceramic welding art would look to the flame-spraying art or the furnace wall combustion art.

**A. Claims 1-12, 19, and 20 are not Anticipated by Myerson '935 or Publication No. US2003/0024470.**

Claims 1-12,19, and 20 are not anticipated by US Patent Application No. 09/918935 (Myerson '935) or US Patent Publication No. US2003/0024470, which is the

Publication of Myerson '935 (collectively, hereinafter "Myerson '935) because Myerson '935 does not disclose every element claimed in the cited claims.

More specifically, Myerson '935 is a Protein Crystal Line invention and discloses a method for the non-photochemical laser induced nucleation in which short high-intensity laser pulses are used to induce nucleation in supersaturated solutions including protein solutions so as to allow the growth of higher quality crystals. Myerson '935 is directed specifically to the laser-induced nucleation of protein crystals in a particular solution. In fact, the method in Myerson '935 as claimed requires "subjecting the supersaturated solution to the light ... so as to induce nucleation of the protein." Thus, the laser causes the nucleation of the solution.

Myerson '935 is not concerned with the production of polymorphs but rather the crystallization or nucleation of a solution without respect to polymorphs. In fact, **Myerson '935 does not disclose the word "polymorph" in the specification**. As such, a person of skill in the art may use Myerson '935 to prepare crystals without knowledge of polymorphs and to produce crystals known in the art. Whether the nucleated protein crystal formed using the Myerson '935 method is a polymorph is irrelevant to the Myerson '935 invention.

In contrast, the present invention as claimed is directed towards a method for preparing crystal polymorphs and not for nucleating protein solutions. By the actual claim limitations, the method in Claims 1-12 includes subjecting a solution to light so to ***"induce the onset of nucleation of the crystal of the polymorph"*** and to "***[grow] the crystal of the polymorph***". As the remainder of the claims (19 and 20) are dependent directly or ultimately from one of the independent Claims 1 and 11, respectively, each of these dependent claims also includes such a limitation. As such, the present invention is not directed to preparing crystal structures in general, nucleating crystals, growing higher quality crystals or nucleating crystals of proteins, but rather specifically to preparing crystal structures with a particular polymorph that do not nucleate under ordinary conditions. As a crystal polymorph of a substance can have significantly different properties from another polymorph of the same substance, a person of ordinary skill in the art needs some knowledge of polymorphs to understand the invention. Myerson '935, on the other hand, as disclosed and claimed, is for a method

for nucleating and growing higher purity protein crystals, which inherently have known or easily discernable properties.

More importantly, even if Myerson '935 teaches the preparation of a protein crystal using a similar method as in the present invention (that is, both inventions use the same "tools", as that term is used in Section 4 above), Myerson '935 does not suggest or teach such a combination of elements to prepare a crystal structure with an extraordinary polymorph. Specifically, one of ordinary skill in the art would not without Applicant's present invention select a wavelength to create a polymorph crystal that does not ordinarily nucleate under ordinary conditions. In Myerson '935, the method involves selecting a wavelength for growing a crystal of a known substance so to grow a better quality crystal in a shorter period of time. While crystals may inherently have polymorphs (as the examiner noted), this is entirely irrelevant to a comparison of the current invention and the Myerson '935 invention, and one of skill in the art need not select a wavelength that nucleates a crystal with a different polymorph just because the art suggests that known protein crystals can be nucleated by a wavelength of light, even if the selected wavelengths are similar or identical. Specifically, following the teachings of Myerson '935, one of ordinary skill in the art will select a wavelength for the nucleation of a known protein crystal, which is not necessarily related to the wavelength needed to nucleate a polymorph that does not ordinary occur.

Without Applicant's present invention, one of ordinary skill in the art would not use a laser or light to generate a polymorph of a crystal that is different than the known polymorph of that crystal. Specifically, under ordinary situations, one of ordinary skill in the art can select a wavelength that can generate a particular crystal polymorph based on the known parameter, as is the case in the urea-water system. In fact, based on the Myerson '935 disclosure, one of ordinary skill in the art would only select a wavelength to produce a known protein crystal or one that ***does*** occur ordinarily. After the present invention, one of ordinary skill in the art would subject a supersaturated solution so to create crystals with polymorphs that do not ordinary occur.

Paradoxically, as many of the new crystal polymorphs, as claimed in Claims 19-20, would not come into fruition without Applicant's method, persons of ordinary skill in the art would not be using a method, such as the one in Claims 1 or 11, to produce

these polymorphs crystals. In fact, in the present method, one of ordinary skill in the art will be selecting wavelengths that produce polymorphs of crystals that do not ordinarily nucleate in a solution. As these crystals have not been produced absent Applicant's method, Applicant provides a method to create such crystals and claims such crystals as part of his invention. As this is now a specific limitation in Claims 19 and 20, Applicant's present invention as claimed in Claims 19 and 20 is not disclosed in Myerson '935.

As such, Myerson '935 cannot and does not anticipate Claims 1-11, 19 and 20. For these reasons, Applicant requests that the examiner withdraw the rejection based on Myerson '935.

**B. Claims 11-20 are not Anticipated by the Garetz Article.**

Claims 11-20 are not anticipated by the Garetz Article, which was also cited against parent application, now US Patent No. 6426406 (Myerson '406). During the prosecution of Myerson '406, the same examiner acknowledged that the Garetz Article does not disclose a method for preparing polymorphs in which the know substance is a not urea.

In lieu of resubmitting previous and further arguments that the Garetz Article does not anticipate Claims 11-18, Applicant has amended independent Claim 11 to include a negative limitation that the known substance is not urea. As the examiner has indicated that the Garetz Article does not teach a method in which the known substance is not urea, Applicant submits that Claims 11-18 are not anticipated by the Garetz Article particularly in light of the inserted negative limitation. As such, Applicant requests that the examiner withdraw the rejection to Claims 11-18 based on the Garetz Article.

In Claims 19-20, the products of the method of the present invention are novel and are not anticipated by the art. As Applicant included the limitation that the polymorphs can "only be manufactured using the method as claimed", Applicant submits that such products are not disclosed in the prior art. Further, because Claims 11-18 have priority on Myerson '406, Myerson '406 is not anticipated by the Garetz Article, and the products are not disclosed by Myerson '406, the products also are not

anticipated by the Garetz Article. As such, Applicant maintains that the products by process are novel and not anticipated by the Garetz Article.

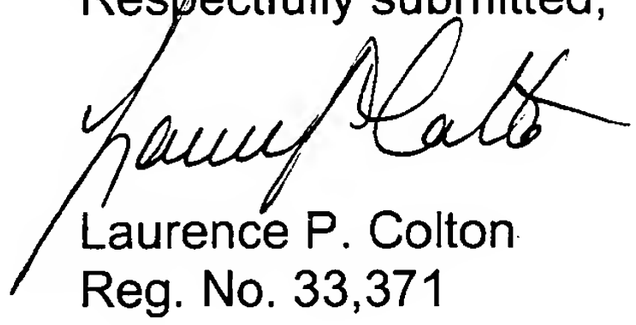
Further, the Merck Index lends nothing to the Garetz Article to create an anticipation situation, as recognized by the examiner in the prosecution of the parent case. The examiner is referred to the discussion submitted during the prosecution of the parent case. If the examiner would like that discussion repeated, Applicant will be happy to do so upon contact by the examiner.

## CONCLUSION

Applicant believes it has fully addressed the examiner's concerns and the claims, as amended, are in condition for allowance, and Applicant respectfully requests such action.

If the examiner has any final concerns that can be addressed over the telephone, the examiner is invited to contact the below-signed patent lawyer of record.

Respectfully submitted,



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